Appendix 1. Literature on values and preferences (RapidRecs PFO Closure)

Search strategy

We searched MEDLINE, EMBASE, and PsycINFO, using subject headings and keywords related to “patent foramen ovale” and “stroke,” with a search filter for values and preferences, from inception to November 16 2017.[1] We also searched the first 5 pages of Google using the terms “patent foramen ovale” and “values and preferences,” on November 16 2017.

Results

After removing duplicates, 455 titles and abstracts were screened. Six studies were reviewed in full text. None of the studies were conducted in patients who had PFO and stroke about their values and preferences regarding management, for example treatment outcome prioritization, or the degree of stroke risk reduction and/or bleeding risk increase deemed important to choose treatment alternatives. In addition, there was an FDA report on the AMPLATZERTM PFO Occluder (St. Jude Medical Inc.) of device safety and effectiveness, which included results from a patient satisfaction survey from the RESPECT trial.[2 3]

Three studies reported on quality of life after PFO closure. Cohen et al. measured the quality of life of patients who had PFO closure after cerebral vascular incidents or transient ischemic attacks, compared to healthy age-matched controls.[4] PFO closure patients had similar ratings of depression, anxiety, and quality of life, and slightly higher optimism than controls. Evola et al. measured quality of life before PFO closure and 6 month after, where 65% of the patient population had cryptogenic stroke.[5] Results suggested improved self-reported physical and mental health outcomes. Feeney-Heinzelmann et al. measured depression and anxiety before and after PFO closure, and reported significant improvements for both outcomes following the procedure.[6]

One abstract reported on a survey of 2157 people recruited via online crowd-sourcing, who were asked to imagine that they had a minor stroke and presented different information about PFO and treatment options.[7] More patients chose PFO closure versus medical treatment when presented with an approximately 3% decrease in stroke risk compared to no difference in stroke (OR 5.5, 95% CI 4.23, 7.13). There was limited description of the survey respondents and the comprehensiveness of the information they were presented.

One study was a commentary about the need for patient-reported outcomes in clinical trial design, with a focus on PFO trials.[8] The authors highlight that there should be longer term follow up, and more detailed measures of physical and emotional outcomes, including physical disability from recurrent strokes, fatigue, emotional distress, and social role participation.

There was a book chapter about PFO patients’ perspectives, which was informed by commonly reported concerns of an online community for persons with PFO (PFO Research Foundation’s Facebook Online Patient Community), and written by the group’s founder.[9] The author highlighted that there was limited and inconsistent information available to patients

and that this varied by the specialist they saw, inconsistent diagnostic testing for cryptogenic stroke, and issues with availability of treatments due to cost and insurance.

Finally, a report from the device manufacturer on the product's safety and efficacy included a patient satisfaction survey.[2] They surveyed 744 RESPECT trial subjects who remained in active follow-up in August 2015, of whom 491 answered (278/408 from the device group, 213/336 from the medication management group). Almost all (97.5%) of device patients were satisfied with their treatment, and most (74.6%) of medication management patients. Almost all (90.7%) of device patients responded that they felt that the benefits of closure outweigh the risks, whereas fewer than half (49.2%) of medication management patients felt this way.

Conclusion

To our knowledge, the only study on PFO patients' values and preferences regarding treatment options post-stroke was the RESPECT trial's patient satisfaction survey from a report by the device manufacturers. Several studies reported quality of life before and after PFO closure, and suggested improved mental and physical health outcomes. Reports on PFO patients' perspectives highlights the need for shared decision-making between patients and healthcare providers that is more informative to patients about their available options.

References

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